

**PART 5—DELEGATIONS OF
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AUTHORITY: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

SOURCE: 42 FR 15560, Mar. 22, 1977, unless otherwise noted.

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§ 5.10 Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.

(a) The Assistant Secretary for Health has redelegated to the Commissioner of Food and Drugs, with authority to redelegate except when specifically prohibited, all authority delegated to the Assistant Secretary for Health by the Secretary of Health and Human Services, as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), the Filled Milk Act (21 U.S.C. 61–63), the Federal Import Milk Act (21 U.S.C. 141 *et seq.*), the Tea Importation Act (21 U.S.C. 41 *et seq.*), the Federal Caustic Poison Act (44 Stat. 1406), and The Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), pursuant to section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigations); section 307 (International Cooperation); and section 311 (Federal-State Cooperation) of the Public Health Service Act (42 U.S.C. 241, 242l, 243), as amended, which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under sections 354 through 360F of the Public Health Service Act (42 U.S.C. 263b through 263n), as amended, which relate to electronic product radiation control.

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(4) Functions vested in the Secretary under section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiologic agents under 42 CFR 72); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration.

(5) Functions vested in the Secretary under sections 351 and 352 of part F, subpart 1 of the Public Health Service Act (42 U.S.C. 262 and 263), as amended, Biological Products, insofar as they relate to the functions assigned to the Food and Drug Administration.

(6) Functions vested in the Secretary under section 302(a) of the Public Health Service Act (42 U.S.C. 242(a)), as amended, which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(7) Functions vested in the Secretary under section 303 of the Public Health Service Act (42 U.S.C. 242a), as amended, which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Pub. L. 91-513 for which an investigational new drug application is filed with the Food and Drug Administration and with respect to all drugs not scheduled under Pub. L. 91-513.

(8) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(9) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) which relate to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances list-

ed in Schedule I of the Act, and the merits of the research protocol.

(10) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*) which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(11) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(12) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(13) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

(14) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(15) Function of issuing all regulations of the Food and Drug Administration, except as provided in § 5.11. The reservation of authority contained in Chapter 2-000 of the Department Organization Manual shall not apply.

(16) Functions vested in the Secretary under section 1103 of Executive Order 11490, as amended by Executive Order 11921, which relate to emergency health functions as they pertain to the operations and functional responsibilities assigned to the agency. This authority shall be exercised in accordance with section 102 and pertinent sections of part 30 of Executive Order 11490 and guidelines promulgated by the Federal Preparedness Agency of the General Services Administration; Office of the Secretary, HHS; and Office of the Assistant Secretary for Health.

(17) Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.

(18) Functions vested in the Secretary under the Federal Advisory Committee Act, Public Law 92-463, to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b)

and therefore may be closed to the public for those committees under the administrative jurisdiction of the Commissioner of Food and Drugs. This authority may be redelegated to a single official who reports directly to the Commissioner of Food and Drugs. This authority is to be exercised in accordance with the requirements of the Federal Advisory Committee Act and only with respect to the following:

(i) Meetings, to the extent that they directly involve review, discussion or consideration of records of the Department which are exempt from disclosure under 5 U.S.C. 552(b) (4), (6), and (7), namely, (a) records containing trade secrets and commercial or financial information obtained from a person and privileged or confidential; (b) personnel, medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (c) investigatory files compiled for law enforcement purposes;

(ii) Meetings to the extent that they involve the review, discussion, and evaluation of specific drugs and devices regulated by FDA which are intended to result in recommendations for regulatory decisions under the Federal Food, Drug, and Cosmetic Act and which are concerned with matters listed in 5 U.S.C. 552(b) (4), (5), and (7);

(iii) Meetings held for the sole purpose of considering and formulating advice which the committee will give or any final report it will render, *Provided*:

(a) The meetings will involve solely the internal expression of views and judgments of the members and it is essential to close the meeting or portions thereof to protect the free exchange of such views and avoid undue interference with agency or committee operations, and such views if reduced to writing would be protected from mandatory disclosure under 5 U.S.C. 552(b);

(b) The meeting is closed for the shortest time necessary, summarizing the work of the committee during the closed session, and a report, prepared by the executive secretary will be made available promptly to the public.

(c) When feasible, the public is given a timely opportunity to present rel-

evant information and views to the committee; and

(d) Concurrence for closing the meetings for such purpose is obtained from the Office of the General Counsel and the Office of Public Affairs.

(19) Functions vested in the Secretary under the second sentence of section 310(a) and under section 310(b) (Health Conferences and Health Education Information) of the Public Health Service Act (42 U.S.C. 242o), as amended, to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration, and to issue information related to health for the use of the public and other pertinent health information for the use of persons and institutions concerned with health services when such information is related to the functions of the Food and Drug Administration.

(20) Functions vested in the Secretary under section 2101 of the Public Health Service Act (42 U.S.C. 219) as amended, to accept offers of gifts, excluding the acceptance of gifts of real property. Only the authority to accept unconditional gifts of personal property valued at \$5,000 or less may be redelegated.

(21) Functions vested in the Secretary under section 362 of the Public Health Service Act (42 U.S.C. 265), as amended, which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(22) Functions vested in the Secretary under section 1003(b)(3), title X, of the Public Works and Economic Development Act of 1965 (42 U.S.C. 3246b(b)(3)) to waive any matching requirements for programs or projects of State and local governments funded

under title X of that act where it is determined that State or local governments concerned cannot reasonably obtain any non-Federal contributions.

(23) Functions vested in the Secretary under section 401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Pub. L. 94–317 (42 U.S.C. 4831(a)) relating to the prohibition of the application of lead-based paint to cooking, drinking, or eating utensils.

(24) Functions vested in the Secretary for the health information and health promotion program under title XVII of the Public Health Service Act (42 U.S.C. 300u *et seq.*), as amended, insofar as the authorities pertain to functions assigned to the Food and Drug Administration. The delegation includes, but is not limited to, the authorities under: section 1702(a) (1) and (3) and section 1704 (1), (2), and (6). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS–12 and above) positions; promulgate regulations; and submit reports to the President.

(25) To administer a Small Business Innovation Research Program under section 9 of the Small Business Act (15 U.S.C. 638), as amended. The delegation excludes the authority to promulgate regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.

(26) Functions vested in the Secretary under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. 10007 and 10008), as amended. The delegation excludes the authority to promulgate regulations and submit reports to Congress. The authority delegated under section 983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

(27) Functions vested in the Secretary under section 156 of title 35 of the U.S. Code (35 U.S.C. 156), as amended, which allows for the extension of patent terms for human drug products, medical devices, food additives, and color additives subject to the Federal Food, Drug, and Cosmetic Act. These authorities may be redelegated except the authority to make due diligence

determinations under section 156(d)(2)(B), which may not be redelegated to an Office below the Office of the Commissioner of Food and Drugs.

(28) Functions vested in the Secretary under section 1862(h) (1), (2)(A), and (3) of the Social Security Act (42 U.S.C. 1395y (h)(1), (2)(A), and (3)), as amended, which provides for a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this title. The approval and issuance of regulations under that section are reserved to the Secretary, as provided in 21 CFR 5.11.

(29) Functions vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*) (the Act), as amended, and under Executive Order No. 12591 of April 10, 1987, as they pertain to the functions of the Food and Drug Administration. The delegation excludes the authority to promulgate regulations and submit reports to Congress; under section 11(a)(2) of the Act (15 U.S.C. 3710a(a)(2)) to approve agreements and contracts with invention management organizations; and under section 11(c)(3)(B) of the Act (15 U.S.C. 3710a(c)(3)(B)) to propose necessary statutory changes regarding conflict of interest.

(i) The authorities under sections 11(c)(5) (A) and (B) of the Act (15 U.S.C. 3710a(c)(5) (A) and (B)) to disapprove or require the modification of cooperative research and development agreements and licensing agreements after the agreement is presented to the Commissioner of Food and Drugs by the head of the laboratory concerned, and to transmit written explanation of such disapproval or modification to the head of the laboratory concerned, may be redelegated only to a senior official in the immediate office of the Commissioner.

(ii) The following authorities may not be redelegated: The authority under section 11(b)(3) of the Act (15 U.S.C. 3710a(b)(3)) to waive a right of ownership which the Federal Government may have to an invention made under a cooperative research and development agreement; the authority under section 11(b)(4) of the Act (15 U.S.C. 3710a(b)(4)) to permit employees or former employees to participate in

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efforts to commercialize inventions they made while in the service of the United States; the authority under section 11(c)(3)(A) of the Act (15 U.S.C. 3710a(c)(3)(A)) to review employee standards of conduct for resolving potential conflicts of interest; the authority under section 13(a)(1) of the Act (15 U.S.C. 3710c(a)(1)) to retain any royalties or other income, except as provided in section 13(a)(2) of the Act (15 U.S.C. 3710c(a)(2)); and the authority under section 13(a)(1)(A)(i) of the Act (15 U.S.C. 3710c(a)(1)(A)(i)) to pay royalties or other income the agency receives on account of an invention to the inventor if the inventor was an employee of the agency at the time the invention was made.

(iii) Any authorities under paragraph (a)(29) of this section delegated by the Commissioner of Food and Drugs may not be further redelegated.

(30) Functions vested in the Secretary under sections 4702, 4703, and 4704 of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401-1403) which relate to pesticide monitoring and enforcement information, foreign pesticide information, and pesticide analytical methods. The delegation excludes the authority to submit reports to Congress.

(31) Functions vested in the Secretary under the Government Patent Policy Act of 1980 as amended by the Federal Court Reorganization Act of 1984, as they pertain to the functions of the Food and Drug Administration (FDA). The delegated authorities, to be exercised in compliance with all existing rules and regulations regarding patent and invention rights and responsibilities, are restricted to the extent that 35 U.S.C. 203, as amended, may not be redelegated and that under 35 U.S.C. 207(a), the Assistant Secretary for Health is to be notified of any significant invention, patent, or license, so that the Assistant Secretary for Health may decide whether or not documentation concerning any such invention, patent, or license should be submitted to the Assistant Secretary for Health for signature. All other authorities may be redelegated to officials at the level equivalent to bureau and institute directors.

(i) Disposition of rights, 35 U.S.C. 202(c)(7), as amended: The authority to permit a nonprofit organization to assign the rights to a subject invention in the United States to organizations which do not have as one of their primary functions the management of inventions.

(ii) Disposition of rights, 35 U.S.C. 202(d), as amended: The authority to permit a contractor to grant requests for retention of rights by the inventor.

(iii) Disposition of rights, 35 U.S.C. 202(e), as amended: The authority to transfer or assign whatever rights FDA may acquire in the subject invention in any case when an agency employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm. Such rights may be transferred or assigned from the FDA employee to the contractor subject to the conditions set forth in this chapter.

(iv) March-in-rights, 35 U.S.C. 203, as amended: The authority to require the contractor to grant nonexclusive, partially exclusive, or exclusive licenses to responsible applicant(s), or the authority for FDA to grant such licenses, provided such action would be in the best interest of FDA, in accordance with all provisions of this section.

(v) Preference for United States industry, 35 U.S.C. 204, as amended: The authority to waive the preference for U.S. industry requirement.

(vi) Domestic and foreign protection of federally owned inventions, 35 U.S.C. 207(a) as amended, the authority to:

(A) Apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(B) Grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of title 35 as determined appropriate in the public interest;

(C) Undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract; and

(D) Transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(vii) Determination as to domestic rights and notice to employee of determination, 45 CFR 7.3 and 7.7, as amended, authority to:

(A) Leave title to invention in the FDA employee inventor where the Government has insufficient interest in an invention to obtain the entire domestic right, title, and interest therein; and

(B) Notify the FDA employee inventor of the determination in writing.

(32) Functions vested in the Secretary under sections 2312(a)(1) and (2)(B), (b), and (c) (Use of Investigational New Drugs with Respect to Acquired Immunodeficiency Syndrome); 2314(c) (Scientific and Ethical Guidelines for Certain Treatments); and 2317 (d) and (e) (Information Services) of title XXIII of the Public Health Service Act (42 U.S.C. 300cc–12(a)(1) and (2)(B), (b) and (c), 300cc–14(c) and 300cc–17 (d) and (e), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegation excludes the authority to promulgate regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.

(33) Functions vested in the Secretary under section 2672(a)(1) (A) and (B) (Provisions Relating to Blood Banks) and section 2672(a)(2) (Information and Training Programs) of the Public Health Service Act (42 U.S.C. 300ff *et seq.*), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegations exclude the authority to promulgate regulations, submit reports to the Congress, establish advisory committees or national commissioners, and appoint members to such committees or commissions.

(34) Functions vested in the Secretary under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of this section. The delegation excludes the authority to submit reports to Congress.

(35) Functions vested in the Secretary under part C, subtitle 2 of title XXI of the Public Health Service Act (42 U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(i) Section 2125 of the Public Health Service Act (42 U.S.C. 300aa–25)—Recording and reporting of information.

(ii) Section 2127 of the Public Health Service Act (42 U.S.C. 300aa–27)—Mandate for safer childhood vaccines.

(iii) Section 2128 of the Public Health Service Act (42 U.S.C. 300aa–28)—Manufacturer recordkeeping and reporting.

(iv) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies.

(v) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks.

(vi) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information.

(vii) The delegation excludes the authority to issue regulations and submit reports to Congress.

(36) Functions vested in the Secretary under section 354(b) through (l) and (n), (o), (q), and (r) of the Public Health Service Act (section 2 of the Mammography Quality Standards Act of 1992 (Pub. L. 102–539)), as amended, which deal with the certification of mammography facilities. The delegation excludes the authority to submit reports to Congress.

(37) Functions vested in the Secretary under section 811(h)(4) of the Controlled Substances Act (Title II of

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the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended) to provide responses to the Drug Enforcement Administration's temporary scheduling notices. The delegation excludes the authority to submit reports to Congress.

(38) Functions vested in the Secretary under the Safe Medical Devices Act of 1990 (Pub. L. 101-629), as amended. The delegation excludes the authority to submit reports to Congress.

(39) Functions vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104-180), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

(b) The Chief Counsel of the Food and Drug Administration, i.e., the Associate General Counsel in charge of the Food and Drug Division, has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act, section 4 of the Federal Import Milk Act, and section 9(b) of the Federal Caustic Poison Act.

(c) The Director, Office of Management, Public Health Service, has re-delegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the non-existence of records on file within the Administration; and to cause the Seal of the Department of be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(d) The Executive Officer, Public Health Service, has re-delegated to the Commissioner of Food and Drugs appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act

regulations (part 21 of this chapter and 45 CFR part 5b). The authority may not be re-delegated.

(e) [Reserved]

(f) The Secretary of Health and Human Services has re-delegated to the Commissioner of Food and Drugs, or his designee, the authority to take final action on matters pertaining to section 203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop procedures and regulations where necessary to supplement the Department's regulations, 45 CFR part 13.

[42 FR 15560, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §5.10, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§5.11 Reservation of authority.

(a) Notwithstanding provisions of §5.10 or any previous delegations of authority to the contrary, the Secretary reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the

approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

[47 FR 16318, Apr. 16, 1982]

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs is redelegated as set forth in this subpart.

(b) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs and this authority may not be further redelegated:

- (1) Deputy Commissioner;
- (2) Associate Commissioner for Regulatory Affairs;
- (3) Senior Associate Commissioner;
- (4) Deputy Commissioner for Management and Systems;
- (5) Senior Associate Commissioner for Policy, Planning, and Legislation; and
- (6) Deputy Commissioner for International and Constituent Relations.

(c)(1) During the absence or disability of the Commissioner, or in the event of a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

- (i) Deputy Commissioner;
- (ii) Associate Commissioner for Regulatory Affairs; or
- (iii) Senior Associate Commissioner.

(2) This authority may not be further redelegated. However, for a planned period of absence, the Commissioner of Food and Drugs (or someone "acting" on his/her behalf) may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him as "acting" or unless not legally permissible.

(e)(1) The Senior Associate Commissioner is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with §5.10(a)(18). This authority may not be further redelegated.

(2) The Senior Associate Commissioner is authorized to perform other associated advisory committee functions (e.g., establishing technical and scientific review groups (advisory committees)); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees. This authority may not be further redelegated.

(3) The Senior Associate Commissioner is authorized to approve conflict of interest waivers for special Government employees serving on advisory committees in accordance with 18 U.S.C. 208(b)(3), as amended. This authority may not be further redelegated.

(4) The Senior Associate Commissioner is authorized to select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another center. This authority may not be further redelegated.

(f)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized to perform any of the functions of the Commissioner of Food and Drugs with respect to the issuance of FEDERAL REGISTER notices and proposed and final regulations of the Food and Drug Administration. This authority may not be further redelegated.

(2) The Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized to issue responses to the following matters under part 10 of this chapter as follows, and this authority may not be further redelegated:

- (i) Requests for waiver, suspension, or modification of procedural requirements under §10.19 of this chapter;

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(ii) Citizen petitions under §10.30 of this chapter;

(iii) Petitions for reconsideration under §10.33 of this chapter;

(iv) Petitions for stay under §10.35 of this chapter; or

(v) Requests for advisory opinions under §10.85 of this chapter.

(3) With respect to any matter delegated to the Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy under paragraph (f) of this section, the Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized to perform the function of the Commissioner of Food and Drugs under §§10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of this chapter and of the Deputy Commissioner under §10.206(g) and (h) of this chapter. This authority may not be further redelegated.

(4) The Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. This authority may be further redelegated.

(g) The following officials are authorized to perform all of the functions of the officials under them in their respective offices, and this authority may not be further redelegated:

(1) Senior Associate Commissioner;

(2) Deputy Commissioner for International and Constituent Relations;

(3) Deputy Commissioner for Management and Systems; or

(4) Senior Associate Commissioner for Policy, Planning, and Legislation.

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions (under 21 U.S.C. 379h(d)) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. This authority may not be further redelegated. (See §5.101 for the user fee-related re-delegation to officials within the Center for Drug Evaluation and Research.)

(2) The Deputy Commissioner for Management and Systems and the Director, Office of Financial Management are authorized to perform the functions of the Commissioner under 21 U.S.C. 379h(d)(1)(C), as amended, to waive or reduce prescription drug user fees in situations where he/she finds that “the fees will exceed the anticipated present and future costs.” This authority may not be further redelegated.

(3) The Deputy Commissioner or, in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. This authority may not be further redelegated.

(i) The Deputy Commissioner is authorized to perform the due diligence determinations and informal hearings functions under 35 U.S.C. 156(d)(2)(B)(ii), as amended, relative to patent term extensions. This authority may not be further redelegated.

(j) Authority delegated in the following sections of this subpart may not be redelegated.

[43 FR 20487, May 12, 1978, as amended at 48 FR 43300, Sept. 23, 1983; 56 FR 36001, July 30, 1991; 57 FR 12875, Apr. 14, 1992; 58 FR 17095, Apr. 1, 1993; 59 FR 14549, Mar. 29, 1994; 61 FR 2414, Jan. 26, 1996; 62 FR 923, Jan. 7, 1997; 62 FR 48757, Sept. 17, 1997; 63 FR 41960, Aug. 6, 1998; 64 FR 59618, Nov. 3, 1999; 65 FR 34960, June 1, 2000]

§5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health and Human Services regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same

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officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters.

§5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of or extracts from any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the non-existence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, and the Deputy Commissioner for Management and Systems.

(2) The Senior Associate Commissioners, the Associate and Deputy Associate Commissioners, and the Chief Counsel and Deputies.

(3) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner.

(4) The Executive Assistant to the Commissioner, Office of the Commissioner.

(5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).

(ii) The Director and Deputy Director, Office of Regional Operations, ORA.

(iii) The Director and Deputy Director, Office of Resource Management, ORA.

(iv) The Director, Division of Management Operations, and Chief, Administrative Management Branch, Office of Resource Management, ORA.

(v) The Director, FDA History Staff, ORA.

(6)(i) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(ii) The Director, Division of Management Programs, Office of Human Re-

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sources and Management Services, Office of Management and Systems, Office of the Commissioner.

(iii) The Chief, Dockets Management Branch, Division of Management Programs, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(7)(i) The Associate Commissioner for Public Affairs, Office of Public Affairs, Office of the Senior Associate Commissioner, Office of the Commissioner.

(ii) The Director, Freedom of Information Staff, Office of Public Affairs, Office of the Senior Associate Commissioner, Office of the Commissioner.

(8)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Directors and Deputy Directors of the Office of Compliance, CBER.

(iv) The Director of Congressional and Public Affairs Staff, Office of the Center Director, CBER.

(v) The Chief, Surveillance and Policy Branch and Consumer Safety Officers, Office of Compliance, CBER.

(9)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Management Systems, CFSAN.

(iv) The Director, Office of Cosmetics and Colors, CFSAN.

(v) The Director, Office of Plant and Dairy Foods Beverages, CFSAN.

(vi) The Director, Office of Seafood, CFSAN.

(vii) The Director, Office of Special Nutritional, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

(x) The Director, Office of Field Programs, CFSAN.

(xi) The Director, Office of Pre-market Approval, CFSAN.

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(xiii) The Director, Office of Food Labeling, CFSAN.

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(10)(i) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Management and Communications, Center for Veterinary Medicine (CVM).

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(v) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(vi) Freedom of Information Officers, CDRH.

(11)(i) The Director and Deputy Directors, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management and Communications, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(v) The Chief, Case Guidance Branch, Division of Compliance, Office of Surveillance and Compliance, CVM.

(12)(i) The Director and Deputy Director, National Center for Toxicological Research (NCTR).

(ii) The Director, Office of Management, Facilities, and Research Support, NCTR.

(13)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Management, CDER.

(iii) The Director and Deputy Director, Office of Compliance, CDER.

(iv) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, and the Director and Deputy Director of the Office of Epidemiology and Biostatistics, Office of Review Management, CDER.

(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology

and Biopharmaceutics, Office of Pharmaceutical Science, CDER.

(vi) The Chief, Freedom of Information Staff, Office of Training and Communications, CDER.

(vii) The Directors of the Divisions of Labeling and Nonprescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, Office of Compliance, CDER.

(14)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, New York Laboratory Division, Northeast Region.

(v) The Director, Southeast Regional Laboratory, Southeast Region.

(vi) The Director, National Forensic Chemistry Center.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, and the Deputy Commissioner for Management and Systems.

(2) The Senior Associate Commissioners, the Associate and Deputy Associate Commissioners, and the Chief Counsel and Deputies.

(3) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(c) The authorities under § 5.22 (a) and (b), where appropriate, may be further re delegated by the Deputy Commissioners; Senior Associate Commissioners; Associate Commissioner for Regulatory Affairs and Deputy; Chief Counsel and Deputies; Center Directors and Deputies; and Executive Officers (i.e., Executive Assistant, Office of the Commissioner; Director, Office of Management, CBER; Director, Office of Management, CDER; Director, Office of Management and Systems, CFSAN; Director, Office of Systems and Management, CDRH; Director, Office of Management and Communications, CVM; Director, Office of Management, Facilities, and Research Support, NCTR; and the Director, Office of Resource Management, ORA).

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(d) The Chief, Regulations Editorial Section; Regulations Policy and Management Staff; Office of Policy, Planning, and Legislation; Office of the Commissioner, and his/her alternates are authorized to certify true copies of FEDERAL REGISTER documents. The Chief, Regulations Editorial Section; Regulations Policy and Management Staff; Office of Policy, Planning, and Legislation; and the Office of the Commissioner may designate alternates as required.

[50 FR 4858, Feb. 4, 1985, as amended at 58 FR 17095, Apr. 1, 1993; 60 FR 26826, May 19, 1995; 61 FR 9639, Mar. 11, 1996; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997; 64 FR 4965, Feb. 2, 1999; 64 FR 49383, Sept. 13, 1999; 65 FR 34961, June 1, 2000]

§ 5.23 Disclosure of official records.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials listed in paragraph (a)(1) of this section may disclose official records and information under §§ 20.82 and 20.85 of this chapter, and only officials listed in paragraph (a)(10) of this section may disclose information under § 20.89(c) of this chapter.

(1) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, the Deputy Commissioner for Management and Systems, Senior Associate Commissioners, Associate and Deputy Associate Commissioners.

(2)(i) The Executive Assistant to the Commissioner, Office of the Commissioner.

(ii) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner.

(3) Executive Officer, Office of the Commissioner.

(4)(i) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(ii) The Director, Division of Management Programs, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(iii) The Chief, Dockets Management Branch, Division of Management Pro-

grams; Office of Human Resources and Management Services, Office of Management Services, Office of the Commissioner.

(5) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(6) Regional Food and Drug Directors and District Directors.

(7) Director, Winchester Engineering and Analytical Center.

(8) Chiefs of branches Field/District Offices and Centers.

(9) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(10)(i) The Associate Commissioner for Regulatory Affairs, Deputy Associate Commissioner for Regulatory Affairs, and Director, Office of Enforcement, FDA.

(ii) The Director, Deputy Director, and Associate Director for Policy Coordination and Public Affairs, Center for Biologics Evaluation and Research (CBER), and Director, Division of Congressional and Public Affairs, CBER.

(iii) The Director, Deputy Directors, and Associate Director for Science and Medical Affairs, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(v) The Director, Center for Food Safety and Applied Nutrition (CFSAN), and Deputy Director for Systems and Support, CFSAN.

(vi) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(vii) The Director, Deputy Director, and Associate Director for Scientific Coordination, National Center for Toxicological Research (NCTR).

(b) The Chief, Product Information Management Branch, Division of Database Management, Office of Management, Center for Drug Evaluation and Research (CDER), is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records:

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(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy, Division of Program Operations, Office of Compliance, CDRH.

(4) The Chief, Information Processing and Automation Branch, Division of Program Operations, Office of Compliance, CDRH.

(5) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, and the Chief Reporting Systems Monitoring Branch, DSS, OSB, CDRH.

(d) The Director, Office of Resource Management, Office of Regulatory Affairs is authorized to sign affidavits regarding the presence or absence of records in the files of that office.

(e) The Director and Deputy Director, Division of Product Certification, Office of Biological Product Review, Center for Biologics Evaluation and Research, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments.

[43 FR 29286, July 7, 1978, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 51 FR 11428, Apr. 3, 1986; 54 FR 8315, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 37419, July 22, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997; 64 FR 4965, Feb. 2, 1999; 65 FR 34961, June 1, 2000]

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under sections 11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987, except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(29) of this part, as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner of Food and Drugs to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A):

(1) The Director, Center for Biologics Evaluation and Research.

(2) The Director, Center for Devices and Radiological Health.

(3) The Director, Center for Drug Evaluation and Research.

(4) The Director, Center for Food Safety and Applied Nutrition.

(5) The Director, Center for Veterinary Medicine.

(6) The Director, National Center for Toxicological Research.

(7) The Associate Commissioner for Regulatory Affairs.

[53 FR 26049, July 11, 1988]

§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.

(a) The following officials are authorized under sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the act) to establish research, investigation, and testing programs and health information and health promotion programs, which relate to their assigned functions, and to approve grants for conducting such programs:

(1) The Director and Deputy Director, National Center for Toxicological Research.

(2) The Director and Deputy Directors, Centers for Devices and Radiological Health (CDRH).

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(3) The Director and Deputy Director, Center for Biologics Evaluation and Research.

(4) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition.

(5) The Director and Deputy Director, Center for Veterinary Medicine.

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(7) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner.

(b) The Director and Deputy Directors, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program under section 356 of the Act.

(c) The Deputy Commissioner for Management and Systems, Office of Management and Systems, Office of the Commissioner; the Director and Deputy Director, Office of Facilities, Acquisitions, and Central Services, Office of Management and Systems, Office of the Commissioner; the Director, Division of Contracts and Procurement Management, Office of Facilities, Acquisitions, and Central Services, Office of Management and Systems, Office of the Commissioner; and the Chief Grants Management Officer and the Grants Management Officer, Division of Contracts and Procurement Management, Office of Facilities, Acquisitions, and Central Services, Office of Management Systems, Office of the Commissioner are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof for grants approved under the authority delegated in paragraphs (a) and (b) of this section.

(d) The Director of the National Center for Toxicological Research is authorized under section 301, as amended by Pub. L. 95-622, of the Public Health Service Act to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of

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the Center which are not required to support Center research programs.

[45 FR 7783, Feb. 5, 1980, as amended at 45 FR 27924, Apr. 25, 1980; 46 FR 17758, Mar. 20, 1981; 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989; 57 FR 45295, Oct. 1, 1992; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997; 65 FR 34962, June 1, 2000]

§ 5.26 Service fellowships.

Under authority of sections 207(g) and 208(f) of the Public Health Service Act (42 U.S.C. 209(g) and 210(f)), and within the limits of an approved service fellowship plan, the following officials are authorized to designate persons to receive service fellowships, appoint service fellows, and determine specific stipend rates for individual actions within the ranges established under an approved service fellowship plan:

(a) Deputy Commissioners.

(b) The Director and Deputy Director, National Center for Toxicological Research (NCTR), and the Director, Office of Management, NCTR.

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director, Office of Systems and Management, CDRH.

(d) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), the Associate Director for Research, CBER, and Office Directors.

(e) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and Director, Office of Management Systems, CFSAN.

(f) The Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director, Office of Management, CVM.

(g) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), and the Director and Deputy Director, Office of Management, CDER.

(h) The Director, Office of Resource Management, Office of Regulatory Affairs.

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(i) The Director, Office of Human Resources Management, Office of Management and Systems.

[48 FR 56946, Dec. 27, 1983, as amended at 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989; 59 FR 5317, Feb. 4, 1994; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997]

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives; and due diligence determinations.

(a) The Director, Center for Drug Evaluation and Research (CDER) and the Associate Director for Policy, CDER, are authorized to perform the functions delegated to the Commissioner of Food and Drugs under 35 U.S.C. 156, as amended, except for making due diligence determinations and holding of informal hearings under 35 U.S.C. 156(d)(2)(B).

(b) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to perform the functions delegated to the Commissioner to make due diligence determinations under 35 U.S.C. 156(d)(2)(B), as amended, except for holding of informal hearings under 35 U.S.C. 156(d)(2)(B)(ii).

[65 FR 34962, June 1, 2000]

§ 5.28 Cardiac pacemaker devices and pacemaker leads.

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under the Social Security Act (42 U.S.C. 1395y(h)(1), (2)(A), and (3)), as amended.

[62 FR 67270, Dec. 24, 1997]

§ 5.29 Functions pertaining to safer vaccines.

The Director, Center for Biologics Evaluation and Research (CBER), and the Associate Director for Policy Coordination and Public Affairs, CBER, are authorized to perform the functions of the Commissioner of Food and Drugs under part C, subtitle 2 of title XXI of the Public Health Service Act (42

U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(a) Section 2125 of the Public Health Service Act (42 U.S.C. 300aa–25)—Recording and reporting of information.

(b) Section 2127 of the Public Health Service Act (42 U.S.C. 300aa–27)—Mandate for safer childhood vaccines.

(c) Section 2128 of the Public Health Service Act (42 U.S.C. 300aa–28)—Manufacturer recordkeeping and reporting.

(d) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies, except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and 312(d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(e) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks, except that the authority to provide for notice and opportunity for public hearing on the establishment of guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(f) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information.

[58 FR 17106, Apr. 1, 1993]

§ 5.30 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act; section 6 of the Fair Packaging and Labeling Act; section 9(b) of the Federal Caustic Poison Act; and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

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(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(4) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(5) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Directors, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the Public Health Service Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing pursuant to the provisions of part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of §16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office

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of the Senior Associate Commissioner, Office of the Commissioner.

(2) The Director and Deputy Directors, CFSAN.

(3) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Director, CBER, and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

[48 FR 8440, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8316, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997; 65 FR 34962, June 1, 2000]

§5.31 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date in §201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors of the Offices of Biological Product Review and Biologics Research, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Biological Product Review and Biologics Research, CBER.

(2)(i) The Director, Deputy Center Director for Review Management, and

Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iv) The Director and supervisory consumer safety officers, Pilot Drug Evaluation Staff, Office of the Center Director, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter requesting in vitro test modifications under §331.29 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in §211.132, §700.25, or §800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director and Deputy Directors, Center for Devices and Radiological Health.

(d) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter requesting exemption from the general pregnancy-nursing warning for over-

the-counter (OTC) drugs required under §201.63 of this chapter, requesting exemption from a general overdose warning required under §330.1(g) of this chapter, and requesting exemption from OTC drug administrative procedures under §330.10 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e)(1) The following officials are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Cosmetics and Colors, CFSAN.

(iv) The Director, Office of Food Labeling, CFSAN.

(v) The Director, Office of Premarket Approval, CFSAN.

(vi) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(vii) The Director, Office of Seafood, CFSAN.

(viii) The Director, Office of Special Nutritionals, CFSAN.

(2) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(3) The Director and Deputy Director, CBER, are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(4) The Director, Deputy Center Director for Review Management, and

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Deputy Center Director for Pharmaceutical Science, CDER, are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(5) The Director and Deputy Directors, CDRH, are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(f)(1) The Director and Deputy Director, CBER, are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter on drug and biological product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.68 *Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products*;

(ii) Section 5.69 *Notification of release for distribution of biological products*;

(iii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iv) Section 5.80 *Approval of new drug applications and their supplements*; and

(v) Section 5.82 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements*.

(vi) Section 5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment*.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER, are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter on drug product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.70 *Issuance of notices implementing the provisions of the Drug Amendments of 1962 (DESI)*;

(ii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iii)-(iv) [Reserved]

(v) Section 5.75 *Designation of official master and working standards for anti-biotic drugs*;

(vi) Section 5.76 *Certification of anti-biotic drugs*;

(vii) Section 5.78 *Issuance, amendment, or repeal of regulations pertaining to anti-biotic drugs*;

(viii) Section 5.80 *Approval of new drug applications and their supplements*; and

(ix) Section 5.82 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements*.

(x) Section 5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment*.

(3) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, except for those drug products listed in §314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(4) The Director and Deputy Director, Office of Biological Product Review, CBER, for those drug products listed in §314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(5) For drugs assigned to their organization, the following officials are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter from sponsors of an investigational new drug application who request approval to ship in interstate commerce, in accordance with §2.125(j) of this chapter, an investigational new drug for human use containing a chlorofluorocarbon.

(i) The Director and Deputy Director, CBER.

(ii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(6) The Director and Deputy Director, CVM, are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter from sponsors of

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an investigational new animal drug application who request approval to ship in interstate commerce, in accordance with § 21.125(j) of this chapter, an investigational new animal drug for animal use containing a chlorofluorocarbon.

(7) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product.

(8) The Director and Deputy Director, CVM, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter concerning actions they are authorized to take under § 5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(g) The Director and Deputy Directors, CDRH, and the Director, Office of Compliance, CDRH, are authorized to grant or deny citizen petitions submitted under §§ 10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

(h) The Director and the Director of the Office of Compliance, CDER, are each authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting an exception or alternative to any requirement in part 211 of this chapter pertaining to current good manufacturing practice for positron emission tomography radiopharmaceutical drug products.

[47 FR 38480, Aug. 31, 1982]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 5.10, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 5.32 Authority relating to determination of product classification and assignment of primary jurisdiction.

The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, as product jurisdiction officer is authorized to make a determination under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) respecting the classification

of a product as a drug, biological product, device, or a combination product subject to section 503(g) of the act, and to assign primary responsibility respecting the organizational component of the Food and Drug Administration that will regulate the product.

[65 FR 34962, June 1, 2000]

§ 5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug.

For a product that is or contains a biologic, a device, or a drug, the following officials in the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, or Center for Drug Evaluation and Research who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Biological Product Review, CBER.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director, Office of Device Evaluation, CDRH.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

[56 FR 58759, Nov. 21, 1991, as amended at 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997]

§ 5.34 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.

(a) Each center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that center's management to serve temporarily as voting members on another advisory committee under that center's management when expertise is required that is

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not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees if such voting members are serving on an advisory committee managed by another center has not been re-delegated. This authority will continue to be exercised by the Commissioner or the Senior Associate Commissioner, Office of the Commissioner.

(b) Each center director is authorized, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special government employees without substantial interest to serve as consultants to advisory committees or in any other capacity within the centers except as advisory committee members.

[58 FR 39142, July 22, 1993, as amended at 65 FR 34962, June 1, 2000]

§ 5.35 Enforcement activities.

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA-200A, Identification Record, and Form FDA-200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the act); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, and sections 351 and 354 through 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Re-

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organization Plan No. 1 of 1953, effective April 11, 1953.

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA-200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act:

(i) Carry firearms;

(ii) Serve and execute search warrants and arrest warrants;

(iii) Execute seizure by process issued pursuant to libel under section 304 of the act;

(iv) Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(v) Make, prior to the institution of libel proceedings under section 304(a)(2) of the act, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable grounds to believe that they are, subject to seizure and condemnation under section 304(a)(2) of the act.

(2) Perform such other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe.

(3) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(c) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to provide specialized law enforcement support involving criminal investigations under the Federal Food, Drug, and Cosmetic Act (the act), and other

duties as assigned by the Commissioner, and issued the Food and Drug Administration Official Credential consisting of Form FDA-200E, Special Authority for Criminal Investigative Specialists, is authorized to receive information as to all matters relating to such act and regulations promulgated under the act.

(d) The Food and Drug Administration's official credentials referred to in paragraphs (a), (b), and (c) of this section are described as follows:

(1) Form FDA-200A entitled "Identification Record" bears a color photograph, a description, and the signature of the holder, an identification number, an expiration date, the Department of Health and Human Services' seal with blue imprint, on the left of the photograph, and the Food and Drug Administration's symbol, on the right of the photograph.

(2) Form FDA-200B entitled "Specification of General Authority" bears the holder's name, his or her general authority, an identification number, an expiration date, the Commissioner's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. The form is superimposed with the Department's seal with blue imprint.

(3) Form FDA-200D, entitled "Special Authority for Criminal Investigators," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under 21 U.S.C. 334 and 372 and other duties as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigator's badge with blue imprint.

(4) Form FDA-200E, entitled "Special Authority for Criminal Investigative Specialists," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under the act, and other duties under the law, as assigned

by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigative specialist's badge with blue imprint.

[49 FR 19973, May 11, 1984, as amended at 53 FR 22293, June 15, 1988; 56 FR 23788, May 24, 1991; 58 FR 494, Jan. 6, 1993; 58 FR 42496, Aug. 10, 1993; 59 FR 47799, Sept. 19, 1994]

§5.36 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under §1240.20 of this chapter.

[60 FR 15871, Mar. 28, 1995]

§5.37 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 309 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(2)(i) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(3)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition, (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Field Programs, CFSAN.

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(iv) The Director, Division of Enforcement, Office of Field Programs, CFSAN.

(4)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(5)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Compliance, CDER.

(iii) The Associate Director for Medical Policy, CDER.

(iv) The Director, Division of Drug Marketing, Advertising, and Communications, Office of Drug Evaluation I, Office of Review Management, CDER.

(6)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) Chiefs of District Compliance Branches.

(iv) The Director, St. Louis Branch.

(v) The Director, Northeast Regional Laboratory, Northeast Region.

(vi) The Director, Southeast Regional Laboratory, Southeast Region.

(vii) The Director, Winchester Engineering and Analytical Center.

(viii) The Director, National Forensic Chemistry Center.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 539(d) of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(4) The Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH.

(5) Regional Food and Drug Directors; District Directors; the Director,

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St. Louis Branch; the Director, Northeast Regional Laboratory, Northeast Region; the Director, Southeast Regional Laboratory, Southeast Region; the Director, Winchester Engineering and Analytical Center; and the Director, National Forensic Chemistry Center, when such functions relate to:

(i) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter; and

(ii) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in § 1040.20(b) of this chapter.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14933, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 42491, Aug. 18, 1994; 60 FR 15871, Mar. 28, 1995; 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997; 64 FR 4965, Feb. 2, 1999]

§ 5.38 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of written notices.

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Director and Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the act regarding the issuance of written notices.

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

[57 FR 18823, May 1, 1992, as amended at 62 FR 2555, Jan. 17, 1997]

§ 5.39 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(a) Associate Directors, CBER.

(b) Office Directors, CBER.

(c) Division Directors, CBER.

[58 FR 18346, Apr. 9, 1993]

§ 5.40 Issuance of Federal Register documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.

The Director and Deputy Director, Center for Veterinary Medicine (CVM) are authorized to issue FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use related to implementation of the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103-396). This authority may be further redelegated by the Director and Deputy Director, CVM.

[62 FR 43471, Aug. 14, 1997]

§ 5.44 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove applications to export unapproved new drugs and biological products and to issue notices of receipt of such applications:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For new animal drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) The following officials are authorized, under section 802(f) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, CBER.

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For veterinary drugs subject to their jurisdiction:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(c) The following officials are authorized, under section 351(h) of the Public

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Health Service Act, to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Director, CBER.

(2) The Director and Deputy Director, Office of Compliance, CBER.

[52 FR 7269, Mar. 10, 1987, as amended at 54 FR 8317, Feb. 28, 1989; 62 FR 2555, Jan. 17, 1997]

§ 5.45 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of food, drugs (including biological products), devices, or cosmetics imported or offered for import.

(2) Determine whether such articles are in compliance with the FFDCA.

(3) Authorize relabeling or other compliance actions to bring articles into compliance under the FFDCA.

(4) Supervise such compliance actions.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug Directors; District Directors; and the Director, St. Louis Branch, are authorized, under section 360 of the Public Health Service Act (PHSA), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of electronic products imported or offered for import to determine whether such products are in compliance with the PHSA.

(2) Refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal.

(3) Supervise operations to bring noncomplying products into compliance under the PHSA.

(4) Refuse or grant permission and time extensions to bring noncomplying products into compliance with the PHSA in accordance with a corrective action plan approved by the Director,

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Office of Compliance and Surveillance, CDRH.

(c) The following officials are authorized, under section 360B(b) of the PHSA, to exempt persons from issuing a certification, as required by section 358(h) of the PHSA, for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations:

(1) The Director and Deputy Directors, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) Regional Food and Drug Directors.

(4) District Directors.

(5) The Director, St. Louis Branch.

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the PHSA that refers to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to exportation of medical devices under section 801(e) of the FFDCA:

(1) For medical devices assigned to their respective organization:

(i) The Director and Deputy Directors, CDRH.

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(v) The Director and Deputy Director, Office of Compliance, CBER.

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(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs, for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the FDCA for emergency medical care:

(1) The Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance, CBER.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 572, Jan. 5, 1984; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 6518, Feb. 13, 1989; 54 FR 8317, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997]

§ 5.46 Manufacturer's resident import agents.

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under § 1005.25(b) of this chapter.

[62 FR 67271, Dec. 24, 1997]

§ 5.47 Detention of adulterated or misbranded medical devices.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(a) For medical devices assigned to their respective organizations:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(4) The Director and Deputy Director, Office of Compliance, CBER.

(b) Regional Food and Drug Directors.

(c) District Directors.

(d) The Director, St. Louis Branch.

[48 FR 8442, Mar. 1, 1983, as amended at 48 FR 56947, Dec. 27, 1983; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 62 FR 67271, Dec. 24, 1997]

§ 5.49 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997]

§ 5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) and denials of petitions for reclassification of medical devices that are submitted under

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section 513(e) of the act (except for petitions submitted in response to FEDERAL REGISTER notices initiating standard-setting under section 514(b) of the act or premarket approval under section 515(b) of the act):

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 54 FR 11866, Mar. 22, 1989; 62 FR 67271, Dec. 24, 1997]

§5.51 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, pursuant to section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, pursuant to section 513 (f)(1)(A) of the act:

(1) The Director and Deputy Directors, CDRH, and the Director, Deputy Directors, Chief of the Premarket Notification Section, Division and Deputy Division Directors, Associate Division Directors, and Branch Chiefs, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, CBER.

[55 FR 6974, Feb. 27, 1990, as amended at 60 FR 2014, Jan. 6, 1995; 62 FR 67271, Dec. 24, 1997]

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§5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997]

§5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, and the Division Directors, ODE, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act:

(i) The Director and Deputy Directors, CDRH, the Director and Deputy

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Directors, ODE, CDRH, and the Division Directors, ODE, CDRH.

(ii) The Director and Deputy Director, CBER, and the Director and Deputy Director, Office of Biological Product Review, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Directors, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515(d), (e), and (g) and 520(h)(1) of the act.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 21708, May 23, 1984; 50 FR 9424, Mar. 8, 1985; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997; 63 FR 27207, May 18, 1998]

§ 5.54 Determinations that medical devices present unreasonable risk of substantial harm.

The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the

Director and Deputy Director, Office of Compliance, CDER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40316, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.55 Orders to repair or replace, or make refunds for, medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518 (b) and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.56 Recall authority.

The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act, which have been delegated to the Commissioner of Food and Drugs:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

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(d) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.57 Temporary suspension of a medical device application.

The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act, to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

(c) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(d) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(e) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.58 Orphan products.

(a) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to

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issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for biologics licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act.

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act.

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act.

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act, with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of

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Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

[48 FR 40703, Sept. 9, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 27489, July 5, 1984; 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997; 64 FR 56448, Oct. 20, 1999; 65 FR 34962, June 1, 2000]

§ 5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For medical devices assigned to their respective divisions, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14934, Apr. 16, 1984; 54 FR 8318, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 62 FR 67272, Dec. 24, 1997]

§ 5.60 Required and discretionary postmarket surveillance.

(a) For any device (including any device that is or contains a drug or biologic) that was first introduced or delivered for introduction into interstate commerce after January 1, 1991, and that is either a permanent implant, the failure of which may cause serious adverse health consequences or death, a life-sustaining or life-supporting device, or a device that potentially presents a serious risk to human health, any of the following officials is authorized to require a manufacturer of such device to conduct postmarket surveillance:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Division Directors and Associate Division Directors, Office of Device Evaluation, CDRH.

(5) The Chief, Premarket Notification Section; Chief, Premarket Approval Section; Director, Program Operations Staff, Office of Device Evaluation, CDRH.

(6) The Director and Deputy Director, Office of Compliance, CDRH.

(7) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(8) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(9) The Director and Deputy Director, Office of Compliance, CDER.

(10) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(11) The Director and Deputy Director, Office of Compliance, CBER.

(12) The Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For any device (including any device that is or contains a drug or biologic), any of the following officials is

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authorized to require a manufacturer of a device to conduct postmarket surveillance if the official determines that postmarket surveillance of the device is necessary to protect the public health or provide safety or effectiveness data for the device:

(1) The Director and Deputy Directors, CDRH.

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Compliance, CDRH.

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(7) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(8) The Director and Deputy Director, Office of Compliance, CDER.

(9) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(10) The Director and Deputy Director, Office of Compliance, CBER.

(11) The Director and Deputy Director, Office of Biological Product Review, CBER.

[57 FR 40315, Sept. 3, 1992, as amended at 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the as-

signed functions of the respective Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all of the functions of the Commissioner of Food and Drugs under sections 409 and 721 of the act regarding the approval of the use of food additives under section 409(e) of the act and the listing of color additives under section 721(d) of the act where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of notices of temporary permits for foods varying from standards of identity under §130.17 of this chapter:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner of Food and Drugs regarding approvals of the

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use of food additives under section 409(e) of the act, where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act or to color additive petitions under section 721(d)(1) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director, Division of Product Policy, Office of Premarket Approval, CFSAN.

(v) The Director, Division of Petition Control, Office of Premarket Approval, CFSAN.

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 721 of the act:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Cosmetics and Colors, CFSAN.

(e) The following officials are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under §130.6 of this chapter:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming generally recognized as safe (GRAS) status of food substances under §170.35 or §570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director and Deputy Director, CVM.

(g)(1) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuance of decisions to grant or deny petitions for nutrient content claims and health claims that do not present controversial issues and regarding the issuance of any notices of proposed rulemaking that result from such action:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the “threshold of regulation” under §170.39 of this chapter:

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(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

(i) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409(h) of the act, excluding the duties set out in section 409(h)(5) of the act, regarding premarket notification of food-contact substances:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Regulations and Policy, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

[49 FR 14936, Apr. 16, 1984, as amended at 49 FR 48183, Dec. 11, 1984; 52 FR 5951, Feb. 27, 1987; 58 FR 2410, Jan. 6, 1993; 59 FR 42492, Aug. 18, 1994; 60 FR 36594, July 17, 1995; 64 FR 33194, June 22, 1999]

§5.62 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under §108.5 of this chapter.

(b) The following officials are authorized to issue notices of confirmation of effective date of final regulations on food matters promulgated under section 701(e) of the Federal Food, Drug, and Cosmetic Act:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(4) The Director, Office of Special Nutritionals, CFSAN.

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(5) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(6) The Director, Office of Seafood, CFSAN.

(7) The Director, Office of Field Programs, CFSAN.

(8) The Director, Office of Premarket Approval, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

[48 FR 8442, Mar. 1, 1983, as amended at 54 FR 9034, Mar. 3, 1989; 60 FR 15871, Mar. 28, 1995]

§5.64 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

The Director and Deputy Director, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter; which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of these sections. The delegation excludes the authority to submit reports to the Congress.

[57 FR 43398, Sept. 21, 1992]

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§ 5.66 Approval of schools providing food-processing instruction.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(b) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(c) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

The Center Director and Deputy Center Directors, Center for Biologics Evaluation and Research are authorized to issue:

(a) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(b) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(c) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

(d) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

(e) Notice of license suspensions under § 601.6 of this chapter.

[50 FR 30697, July 29, 1985, as amended at 54 FR 8318, Feb. 28, 1989; 56 FR 25025, June 3, 1991; 64 FR 47669, Sept. 1, 1999; 64 FR 56448, Oct. 20, 1999]

§ 5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The following officials are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8318, Feb. 28, 1989]

§ 5.69 Notification of release for distribution of biological products.

The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 699) of this chapter:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

(c) The Director and Deputy Director, Division of Product Quality Control, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989]

§ 5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.

The Director, Deputy Center Director for Review Management, and Deputy Director, Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the

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provisions of section 505 of the Federal Food, Drug, and Cosmetic Act.

[62 FR 2556, Jan. 17, 1997, as amended at 64 FR 398, Jan. 5, 1999]

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of this chapter and in animals under § 312.160 of this chapter:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under § 312.44(b)(1)(viii) of this chapter:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in § 312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

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(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 52 FR 7829, Mar. 13, 1987; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997]

§ 5.72 Authority to approve and to withdraw approval of a charge for investigational new drugs.

The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under § 312.7(d)(1) of this chapter:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

[55 FR 5445, Feb. 15, 1990, as amended at 62 FR 2556, Jan. 17, 1997]

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those

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drugs listed in §314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), for drugs listed in §314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under §314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in §5.10(a) and paragraph (a) of this section.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or 505(b)(2) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate cir-

cumstances, continue to be acted upon by the officials so authorized in §5.10(a) and paragraph (a) of this section.

(1) For drugs submitted under §§314.50, 314.70, and 314.94 of this chapter, except for those drug products listed in §314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors and Deputy Directors of the divisions in Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2)(i) For drug products listed in §314.440(b) and submitted under §§314.50, 314.70, and 314.94 of this chapter:

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in §§314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) Associate Director for Chemistry, Office of Pharmaceutical Science, CDER.

(e) The Director, Division of Labeling and Program Support, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs with respect

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to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in §§314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this paragraph.

(f) The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in §§314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in §5.10(a) and paragraphs (a) and (b) of this section.

[49 FR 14935, Apr. 16, 1984, as amended at 50 FR 30697, July 29, 1985; 50 FR 47207, Nov. 15, 1985; 52 FR 37764, Oct. 9, 1987; 54 FR 8319, Feb. 28, 1989; 55 FR 6247, Feb. 22, 1990; 55 FR 51688, Dec. 17, 1990; 57 FR 17980, Apr. 28, 1992; 58 FR 17094, Apr. 1, 1993; 59 FR 33431, June 29, 1994; 60 FR 57338, Nov. 15, 1995; 62 FR 2557, Jan. 17, 1997]

§5.81 Responses to Drug Enforcement Administration temporary scheduling notices.

The Director, Center for Drug Evaluation and Research (CDER) and the Director, Executive Operations Staff, Office of the Center Director, CDER are authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under the Controlled Substances Act, as amended (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 811(h)(4), as amended hereafter). The delegation excludes the authority to submit reports

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to Congress. Further redelegation may only be authorized with the Commissioner of Food and Drugs' approval.

[65 FR 34962, June 1, 2000]

§5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in §314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research, for those drugs listed in §314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

[54 FR 8319, Feb. 28, 1989, as amended at 62 FR 2558, Jan. 17, 1997]

§5.83 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications,

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and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted pursuant to section 512 of the act:

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to new animal drug applications that are described by § 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs pursuant to section 512(m) of the act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of

Animal Feeds, Office of Surveillance and Compliance, CVM.

[49 FR 14937, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 53 FR 2225, Jan. 27, 1988; 53 FR 17186, May 16, 1988; 53 FR 40055, Oct. 13, 1988; 63 FR 70650, Dec. 22, 1998; 64 FR 23184, Apr. 30, 1999]

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted pursuant to section 512(m) of the Federal Food, Drug, and Cosmetic Act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250).

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

[49 FR 17936, Apr. 26, 1984, as amended at 63 FR 70650, Dec. 22, 1998]

§ 5.85 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to issue, renew, and extend certificates to mammography facilities under section 354(c) of the Public Health Service Act (42 U.S.C. 263b):

(1) The Director and Deputy Director for Regulations and Policy, Center for

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Devices and Radiological Health (CDRH).

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(b) The following officials are authorized to accept an application for a certificate under section 354(d)(1) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(c) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(d) The following officials are authorized to ensure that accreditation bodies provide satisfactory assurances of compliance under section 354(e)(1)(C) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(e) The Director, CDRH, is authorized to promulgate regulations under which the Director may withdraw approval of accreditation bodies under section 354(e)(2) of the Public Health Service Act.

(f) The following officials are authorized to determine the applicable standards for a facility for accreditation under section 354(e)(3) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Pro-

grams, Office of Health and Industry Programs, CDRH.

(g) The following officials are authorized to ensure that accreditation bodies make on site visits and to determine whether other measures are appropriate under section 354(e)(4)(A) and (e)(4)(B) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(h) The following officials are authorized to evaluate annually the performance of each approved accreditation body as provided by section 354(e)(6)(A) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(i) The following officials are authorized to determine the compliance of certified facilities with established standards through facility inspections as provided by section 354(g) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(j) The Director and Deputy Director for Regulations and Policy, CDRH, are authorized to impose sanctions under section 354(h)(1) and (h)(2) of the Public Health Service Act.

(k) The Director and Deputy Director for Regulations and Policy, CDRH, are authorized to suspend or revoke individual facility certificates under section 354(i)(1) and (i)(2)(A) of the Public Health Service Act.

(1) The Director and Deputy Director for Regulations Policy, CDRH, are authorized to compile and make available

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to physicians and the general public information the Director determines is useful in evaluating the performance of mammography facilities as provided by section 354(l) of the Public Health Service Act.

(m)(1) The following officials may authorize a State to carry out certification program requirements and implement quality standards under section 354(q)(1) and (q)(2) of the Public Health Service Act:

(i) The Director and Deputy Director for Regulations and Policy, CDRH.

(ii) The Director, Office of Health and Industry Programs, CDRH.

(2) The Director, CDRH, is authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under section 354(q)(4) of the Public Health Service Act.

[60 FR 47268, Sept. 12, 1995]

§ 5.86 Variances from performance standards for electronic products.

The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in subchapter J of this chapter:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

[52 FR 29664, Aug. 11, 1987, as amended at 55 FR 47053, Nov. 9, 1990; 62 FR 67272, Dec. 24, 1997]

§ 5.87 Exemption of electronic products from performance standards and prohibited acts.

The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 358(a)(5) of the Public Health Service Act (the act) and to exempt an electronic product or class of products from all or part of the provisions of section 360B(a) of the act under section 360B(b) of that act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

[52 FR 29664, Aug. 11, 1987, as amended at 55 FR 47053, Nov. 9, 1990; 62 FR 67272, Dec. 24, 1997]

§ 5.88 Testing programs and methods of certification and identification for electronic products.

The Director and Deputy Directors, Center for Devices and Radiological Health, (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 358(g) of the Public Health Service Act (the Act), and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 358(h) of the Act.

[62 FR 67272, Dec. 24, 1997]

§ 5.89 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs, relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 359 of the Public Health Service Act (the act) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in § 1040.20(b) of this chapter.

(b) The Director and Deputy Director, Office of Compliance, CDRH, and

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the Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the act and under §1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in §1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in §1040.20(b) of this chapter.

[48 FR 56948, Dec. 27, 1983, as amended at 51 FR 32452, Sept. 12, 1986; 55 FR 47054, Nov. 9, 1990; 62 FR 15110, Mar. 31, 1997; 62 FR 67272, Dec. 24, 1997]

§5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

[62 FR 67273, Dec. 24, 1997]

§5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

[62 FR 67273, Dec. 24, 1997]

§5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and local authorities

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engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

[62 FR 67273, Dec. 24, 1997]

§5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) of the Federal Food, Drug and Cosmetic Act (the act) concerning the date of submission or the date or effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act and of new drug applications including supplements thereto submitted under section 505(b)(1) of the act and described under section 505(b)(2) of the act:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

[53 FR 18274, May 23, 1988, as amended at 55 FR 6247, Feb. 22, 1990; 62 FR 2558, Jan. 17, 1997; 64 FR 49383, Sept. 13, 1999]

§5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

The following officials are authorized to extend or stay an effective date in §201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(a) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Office of Biological Product Review, CBBER.

(3) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBBER.

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(b) For drugs assigned to their organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

[52 FR 2514, Jan. 23, 1987, as amended at 54 FR 8320, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2558, Jan. 17, 1997]

§ 5.95 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal Food, Drug, and Cosmetic Act (the act) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act, and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act:

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(b) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[56 FR 6263, Feb. 15, 1991]

§ 5.98 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Surveillance and Biometrics, (OSB), CDRH and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

[64 FR 4965, Feb. 2, 1999]

§ 5.99 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director and Associate Director for Policy Coordination and Public Relations, Center for Biologics Evaluation and Research (CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

[61 FR 8215, Mar. 4, 1996; 61 FR 11545, Mar. 21, 1996; 61 FR 14375, Apr. 1, 1996]

Subpart C—Organization

§ 5.100 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under the Regulatory Flexibility Act (5 U.S.C. 605(b)), to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities:

- (a) The Associate Commissioner for Regulatory Affairs (ACRA).
- (b) The Director, Center for Biologics Evaluation and Research (CBER).
- (c) The Director, Center for Drug Evaluation and Research (CDER).
- (d) The Director, Center for Devices and Radiological Health (CDRH).
- (e) The Director, Center for Food Safety and Applied Nutrition (CFSAN).
- (f) The Director, Center for Veterinary Medicine (CVM).
- (g) Other FDA Officials authorized to issue FEDERAL REGISTER documents.

[62 FR 48757, Sept. 17, 1997]

§ 5.101 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Policy, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992, as originally enacted and as reauthorized by the FDA Modernization Act of 1997, except for the functions under 21 U.S.C. 379h(d)(1)(C) that pertain to situations where “the fees will exceed the anticipated present and future costs,” on behalf of CDER, the Center for Biologics Evaluation and Research, and any other FDA center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C. 379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiv-

er provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. These authorities may not be further redelegated. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.)

[64 FR 59618, Nov. 3, 1999]

§ 5.200 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

- OFFICE OF THE COMMISSIONER.¹
- Office of the Chief Counsel.
- Office of Equal Opportunity.
- Office of the Administrative Law Judge.
- Office of the Senior Associate Commissioner.
- Office of Executive Secretariat.
- Office of Public Affairs.
- Office of the Ombudsman.
- Office of Orphan Products Development.
- Office of Internal Affairs.
- Office of Executive Operations.
- Office of International and Constituent Relations.*
- Office of International Programs.
- Office of Consumer Affairs.
- Office of Women’s Health.
- Office of Special Health Issues.
- Office of Policy, Planning, and Legislation.*
- Office of Policy.
- Office of Planning.
- Office of Legislation.
- Office of Management and Systems.*
- Office of Human Resources and Management Services.
- Office of Information Resources Management.
- Office of Financial Management.
- Office of Facilities, Acquisitions, and Central Services.²

¹Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

²Mailing address: 5630 Fishers Lane, Rockville, MD 20852.

Food and Drug Administration, HHS

§ 5.200

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.³

Office of the Center Director.

Scientific Advisors and Consultants Staff.

Equal Employment Opportunity and Workforce Diversity Staff.

Quality Assurance Staff.

Regulations and Policy Staff.

Veterinary Services Staff.

Office of Management.

Regulatory Information Management Staff.

Division of Planning, Evaluation, and Budget.

Division of Management Services.

Office of Information Technology Management.

Division of Information Technology Operations.

Division of Information Technology Development.

Division of Information Technology Infrastructure.

Office of Compliance and Biologics Quality.

Team Biologics Liaison Staff.

Advertising and Promotional Labeling Staff.

Division of Case Management.

Division of Manufacturing and Product Quality.

Division of Inspections and Surveillance.

Office of Blood Research and Review.

Human Tissue Staff.

Policy and Publications Staff.

Division of Emerging and Transfusion Transmitted Diseases.

Division of Hematology.

Division of Blood Applications.

Office of Therapeutics Research and Review.

Division of Cellular and Gene Therapies.

Division of Therapeutic Proteins.

Division of Monoclonal Antibodies.

Division of Clinical Trial Design and Analysis.

Division of Application Review and Policy.

Office of Vaccines Research and Review.

Division of Bacterial, Parasitic, and Allergenic Products.

Division of Viral Products.

Division of Vaccines and Related Products Applications.

Office of Communication, Training, and Manufacturers Assistance.

Division of Disclosure and Oversight Management.

Division of Manufacturers Assistance and Training.

Division of Communication and Consumer Affairs.

Office of Biostatistics and Epidemiology.

Division of Biostatistics.

Division of Epidemiology.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.⁴

Office of the Center Director.

Food Safety Initiatives Staff.

Senior Science Advisor's Staff.

Office of Regulations and Policy.

Regulations Coordination Staff.

Office of Constituent Operations.

Consumer Education Staff.

International Activities Staff.

Industry Activities Staff.

Office of Management Systems.

Safety Management Staff.

Division of Information Resources Management.

Division of Planning and Financial Resources Management.

Division of Management Operations.

Division of Administrative Services Management.

Office of Operations.

Equal Employment Opportunity Staff.

Executive Operations Staff.

Office of Cosmetics and Colors.

Division of Programs and Enforcement Policy.

Division of Science and Applied Technology.

Office of Nutritional Products, Labeling, and Dietary Supplements.

Clinical Research and Review Staff.

Division of Compliance and Enforcement.

Division of Standards and Labeling Regulations.

Division of Nutrition Science Policy.

Division of Research and Applied Technology.

Office of Premarket Approval.

Division of Product Policy.

Division of Petition Control.

³Mailing address: 1401 Rockville Pike, Rockville, MD 20852-1448.

⁴Mailing address: 200 C St. SW., Washington DC 20204.

§ 5.200

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Division of Health Effects Evaluation.
Division of Molecular Biological Research and Evaluation.
Division of Product Manufacture and Use.
Office of Plant and Dairy Foods and Beverages.
Division of Virulence Assessment.
Division of Pesticides and Industrial Chemicals.
Division of Natural Products.
Division of Food Processing and Packaging.
Division of Plant Product Safety.
Division of Dairy and Egg Safety.
Division of Risk Assessment.
Office of Seafood.
Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Special Research Skills.
Division of Toxicology Research.
Division of Microbiological Studies.
Office of Field Programs.
Division of Enforcement and Programs.
Division of HACCP Programs.
Division of Cooperative Programs.
Office of Scientific Analysis and Support.
Division of General Scientific Support.
Division of Mathematics.
Division of Market Studies.
CENTER FOR DRUG EVALUATION AND RESEARCH.¹
Office of the Center Director.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Regulatory Policy Staff.
*Office of Management.*¹
Strategic Planning Staff.⁵
Division of Management and Budget.⁵
Division of Management Services.⁵
*Office of Training and Communication.*¹
Division of Communications Management.
Division of the Medical Library.
Division of Training and Development.
Division of Freedom of Information.

*Office of Compliance.*⁶
Division of Manufacturing and Product Quality.
Division of Prescription Drug Compliance and Surveillance.
Division of Labeling and Non- Prescription Drug Compliance.
*Office of Information Technology.*¹
Quality Assurance Staff.
Technology Support Services Staff.
Division of Data Management and Services.
Division of Applications Development and Services.
Division of Infrastructure Management and Services.
*Office of Medical Policy.*¹
Division of Drug Marketing, Advertising, and Communication¹
Division of Scientific Investigations.⁶
*Office of Review Management.*¹
Advisors and Consultants Staff.²
*Office of Drug Evaluation I.*¹
Division of Cardio-Renal Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology Drug Products.
*Office of Drug Evaluation II.*¹
Division of Metabolic and Endocrine Drug Products.
Division of Pulmonary and Allergy Drug Products.
Division of Anesthetic, Critical Care, and Addiction Drug Products.
*Office of Drug Evaluation III.*¹
Division of Gastrointestinal and Coagulation Drug Products.
Division of Medical Imaging and Radiopharmaceutical Drug Products.
Division of Reproductive and Urologic Drug Products.
Office of Drug Evaluation IV.
Division of Anti-Infective Drug Products.
Division of Anti-Viral Drug Products.
Division of Special Pathogen and Immunologic Drug Products. *Office of Drug Evaluation V.*
Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products.
Division of Dermatologic and Dental Drug Products.
Division of Over-the-Counter Drug Products.

⁵Mailing address: 7500 Standish Pl., Rockville, MD 20855.

⁶Mailing address 7520 Standish Pl., Rockville, MD 20855.

Food and Drug Administration, HHS

§ 5.200

*Office of Biostatistics.*¹
Quantitative Methods Research Staff.

Division of Biometrics I.

Division of Biometrics II.

Division of Biometrics III.

Office of Post-Marketing Drug Risk Assessment.

Extramural Programs Staff.

Information Technology Staff.

Division of Drug Risk Evaluation I.

Division of Drug Risk Evaluation II.

*Office of Pharmaceutical Science.*¹

Quality Implementation Staff.¹

Operations Staff.¹

Office of Clinical Pharmacology and Biopharmaceutics.

Pharmacometrics Staff.

Division of Pharmaceutical Evaluation I.¹

Division of Pharmaceutical Evaluation II.¹

Division of Pharmaceutical Evaluation III.¹

*Office of Generic Drugs.*⁵

Division of Bioequivalence.

Division of Chemistry I.

Division of Chemistry II.

Division of Labeling and Program Support.

*Office of New Drug Chemistry.*¹

Division of New Drug Chemistry I.¹

Division of New Drug Chemistry II.¹

Division of New Drug Chemistry III.¹

*Office of Testing and Research.*¹

Regulatory Research and Analysis Staff.

Laboratory of Clinical Pharmacology.⁷

Division of Applied Pharmacology Research.⁸

Division of Testing and Applied Analytical Development.⁹

Division of Product Quality Research.¹

*Office of Regulatory Affairs.*¹

Contaminants Policy Coordination Staff.

Equal Employment Opportunity Staff.

Strategic Initiatives Staff.

Office of Resource Management.

⁷ Mailing address: Four Research Ct., Rockville, MD 20850.

⁸ Mailing address: 8308 Muirkirk Rd., Laurel, MD 20708.

⁹ Mailing address: 1114 Market St., St. Louis, MO 63101.

Division of Planning, Evaluation, and Management.

Division of Information Systems.

Division of Human Resource Development.

Division of Management Operations.

Division of Personnel Operations.

Office of Enforcement.

Medical Products Quality Assurance Staff.

Division of Compliance Management and Operations.

Division of Compliance Policy.

Office of Regional Operations.

Division of Federal-State Relations.

Division of Field Science.

Division of Emergency and Investigational Operations.

Division of Import Operations and Policy.

Office of Criminal Investigations.

Mid-Atlantic Area Office.¹⁰

Midwest Area Office.¹¹

Northeast Area Office.¹²

Pacific Area Office.¹³

Southeast Area Office.¹⁴

Southwest Area Office.¹⁵

CENTER FOR VETERINARY MEDICINE.¹⁶

Office of the Center Director.

Office of Management and Communications.

Administrative Staff.

Communications Staff.

Program Planning and Evaluation Staff.

Information Resources Management Staff.

Office of New Animal Drug Evaluation.

Division of Therapeutic Drugs for Food Animals.

Division of Biometrics and Production Drugs.

Division of Therapeutic Drugs for Non-Food Animals.

Division of Human Food Safety.

¹⁰ Mailing address: 900 U.S. Courthouse, Second Chestnut St., Philadelphia, PA 19106.

¹¹ Mailing address: 901 Warrenville Rd., suite 360, Lisle, IL 60532.

¹² Mailing address: 850 Third Ave., Brooklyn, NY 11232.

¹³ Mailing address: 13301 Clay St., Oakland, CA 94512.

¹⁴ Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

¹⁵ Mailing address: 7920 Elmbrook Rd., Dallas, TX, 75247.

¹⁶ Mailing address: 7500 Standish Pl., MPN-2, Rockville, MD 20855.

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Division of Manufacturing Technologies.
Office of Surveillance and Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Compliance.
Division of Epidemiology.
Office of Research.
Administrative Staff.
Division of Residue Chemistry.
Division of Animal Research.
Division of Animal and Food Microbiology.
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.¹⁷
Office of the Center Director.
Equal Employment Opportunity Staff.
Office of Systems and Management.
Integrity Committee and Conference Management Staff.
Division of Management Operations.
Division of Information Dissemination.
Division of Information Technology Management.
Division of Planning, Analysis, and Finance.
Office of Compliance.
Promotion and Advertising Policy Staff.
Division of Bioresearch Monitoring.
Division of Program Operations.
Division of Enforcement I.
Division of Enforcement II.
Division of Enforcement III.
Office of Device Evaluation.
Program Management Staff.
Program Operations Staff.
Division of Cardiovascular, Respiratory, and Neurological Devices.
Division of Reproductive, Abdominal, Ear, Nose, Throat, and Radiological Devices.
Division of General and Restorative Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic Devices.
Division of Dental, Infection Control, and General Hospital Devices.
Office of Science and Technology.
Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.

Division of Electronics and Computer Sciences.
Division of Management Information and Support Services.
Office of Health and Industry Programs.
Program Operations Staff.
Regulations Staff.
Staff College.
Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.
Office of Surveillance and Biometrics.
Issues Management Staff.
Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.¹⁸
Office of the Center Director.
Environmental Health and Program Assurance Staff.
Office of Research.
Technology Advancement Staff.
Division of Biochemical Toxicology.
Division of Genetic and Reproductive Toxicology.
Division of Biometry and Risk Assessment.
Division of Microbiology.
Division of Chemistry.
Division of Neurotoxicology.
Division of Veterinary Services.
Division of Molecular Epidemiology.
Office of Management.
Office of Management Services.
Contracts and Procurement Staff.
Division of Facilities, Engineering, and Maintenance.
Division of Administrative Services.
Office of Planning, Finance and Information Technology.
Division of Planning.
Division of Financial Management.
Division of Information Technology.

[65 FR 19830, Apr. 13, 2000]

§ 5.205 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Associate General Counsel, Food and Drug

¹⁷Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

¹⁸Mailing address: 3900 NCTR Dr., Jefferson, AR 72079.

Food and Drug Administration, HHS

§5.215

Division, Office of the General Counsel, Department of Health and Human Services, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981, as amended at 56 FR 8709, Mar. 1, 1991. Redesignated at 62 FR 13824, Mar. 24, 1997]

§ 5.210 FDA Public Information Offices.

(a) *Dockets Management Branch (HFA-305)*. The Dockets Management Branch Public Room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Telephone: 301-827-6860.

(b) *Freedom of Information Staff (HFI-35)*. The Freedom of Information Public Room is located in rm. 12A-30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-827-6567.

(c) *Press Relations Staff (HFI-40)*. The Press Offices are located in rm. 15-05, Parklawn Bldg., 5600 Fisher Lane, Rockville, MD 20857. Telephone: 301-827-6242; and in rm. 3807, FB-8, 200 C St. SW., Washington, DC 20204. Telephone 202-205-4144.

[65 FR 19832, Apr. 13, 2000]

§ 5.215 Field structure.

NORTHEAST REGION

Regional Field Office: 850 Third Ave., Brooklyn, NY 11232.

Northeast Regional Laboratory: 850 Third Ave., Brooklyn, NY 11232-1593.

New York District Office: 850 Third Ave., Brooklyn, NY 11232-1593.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201-2199.

Cincinnati District Office: 6751 Steger Dr., Cincinnati, OH 45237-3097.

Forensic Chemistry Center: 1141 Central Pkwy., Cincinnati, OH 45202-1097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207-3179.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401-1912.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.

New Orleans District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.

Florida District Office: 555 Winderley, suite 200, Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

SOUTHWEST REGION

Regional Field Office: 7920 Elmwood Rd., suite 102, Dallas, TX 75247-4982.

Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225-0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214-3338.

St. Louis Branch: 12 Sunnen Dr., suite 122, St. Louis, MO 63143-3800.

Arkansas Regional Laboratory: 3900 NCTR Rd., Bldg. 14-T, rm. 104, Jefferson, AR 72079-9502.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217.

San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502-7070.

Los Angeles District Office: 19900 MacArthur Blvd., suite 300, Irvine, CA 92715.

Seattle District Office: P.O. Box 3012, Bothell, WA 98021-3012.

Pacific Regional Laboratory, SW.: 1521 West Pico Blvd., Los Angeles, CA 90015-2488.

*Pacific Regional Laboratory, NW.: 22201
23d Dr. SE., Bothell, WA 98021-4421.*

[65 FR 19832, Apr. 13, 2000]

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

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- 7.84 Opportunity for presentation of views before report of criminal violation.
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AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary re-

moval or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. *Product* does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.

(h) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.